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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,867

Applicant(s)

EATON ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-41 have been canceled.
Claims 42, 43, have been amended.
2. Claims 42-51 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Claim Objections

4. Claim 50 and 51 are objected to because of the following informalities: Claim 50 is depended on canceled claim 39 and 51 is depended on claim 50.

Appropriate correction is required.

5. NOTE: The request to delete inventors is not accepted because it was not in the form of a proper petition. It is noted that the fee has been paid.

Specification

6. The objection to the specification under 35 U.S.C. 132 because it introduces new matter into the disclosure is maintained. The response filed 2/2/04 states that the amendments filed 1/8/02 only corrected typographical errors. In response to this the amendment added applications and provisionals that were not claimed in the original filing. The response states that the amendment of 7/16/02 adds four new provisional applications. In response to this these were not originally stated in the priority claim and

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as such this addition is new matter. The added material update the continuation data by adding provisional and PCT applications and incorporates the applications by reference which is not permitted after filing the application (see 35 USC 132(a) and *Dart industries v. Banner*, 636 F.2d 684, 207 USPQ 273 (CA DC 1980)).

Applicant is required to cancel the new matter in the reply to this Office Action.

Rejections Withdrawn

7. The rejection of claims 42-44, 49-51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the completion of the deposit requirements (see page 11 of response).

Response to Arguments

8. The rejection of claims 42-51 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility is maintained.

The response filed 2/2/04 has been carefully considered but is deemed not to be persuasive. The response states that that the application provides data showing that mRNA for PRO180 polypeptide is overexpressed in rectal tumors compared to normal and the invention is useful in diagnosing cancer (see page 9 of response) and even if

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one assumes arguendo that it is more likely than not that there is no correlation between gene expression and increased protein expression, the claimed invention would still have utility as evidenced by the declaration of Dr. Grimaldi (see page 10 of response). In response to this argument, the declaration has been carefully considered but is deemed not to be persuasive. The declaration states that those working in the field are well aware that in the vast majority of cases when a gene is over-expressed as evidenced from increased production of mRNA, the gene product or polypeptide will also be over-expressed (see page 2 of declaration) and cites references to support this argument. In response to this argument, the examiner cited art in the 112 first rejection that supports that mRNA over-expression does not correlate with protein over-expression. While the references cited by applicant may show protein over-expression, there are equally references that show this not to be the case. In addition Chen et al (Molecular and Cellular Proteomics 1:304-313, 2002) underscore the unpredictability in the art as showing that protein expression does not correlate with gene over-expression. Likewise, Genes VI, Benjamin Lewin, 1997, Chapter 29- Regulation of Transcription, 1st page:

"But having acknowledged that control of gene expression can occur at multiple stages, and that production of RNA cannot inevitably be equated with production of protein, it is clear that overwhelming majority of regulatory events occur at the initiation of transcription"

Thus, the references cited by the examiner are examples that the art is unpredictable with regard to protein over-expression.

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9. The rejection of claims 42-51 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained for the reasons above.

10. The rejection of claims 42-51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 2/2/04 has been carefully considered but is deemed not to be persuasive. The response states that the specification has a definition on page 16, lines 3-13 that describe ECD as essentially free of transmembrane and cytoplasmic domains (see page 10 of response). In response to this argument, this still does not describe the ECD it describes what it is not. The response states that "epitope tag" is clear as set out in the specification on page 23, lines 24-30. In response to this the "epitope tag" is indefinite because it is not clear if this is an epitope for an antibody as recited in the specification at the recited page or if it is a protein fused to the polypeptide.

11. The rejection of claims 42-43, and 50-51 (assuming 50 is depended from claim 42) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response states that the claims have been amended to recite a biological activity of "the nucleic acid encoding said polypeptide is amplified in rectal tumors" (see page 11 of the response). In response to this only SEQ ID NO:1 is amplified in tumors which encodes SEQ ID NO:2 and there is no polypeptide that is overexpressed in rectal tumors. The specification does not describe any other nucleic acid that encodes any polypeptide that is 95-99% identical to SEQ ID NO:2 which is encoded by a nucleic acid that is over-expressed in rectal tumors.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

12. The rejection of claims 42-43, 50-51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response states that a functional limitation has been added to recite "the nucleic acid encoding said polypeptide is amplified in rectal tumors" (see page 12 of response). In response to this argument, the specification does not describe how to make polypeptides that are 95-99% identical to SEQ ID NO:2 wherein the nucleic acid

is overexpressed. The specification does not teach a screen or other such molecules. Therefore one would not know how to make such molecules. In addition as the references cited in the rejection demonstrate protein over-expression does not correlate with mRNA over-expression and this was not addressed in the response.

Priority

13. The examiner acknowledges the priority statement filed 7/16/02, however, because the claimed subject matter does not have a substantial asserted utility or a well established utility, the priority date of the claims are given the filing date of the instant application, 12/6/01. It is also noted that if applicant can overcome the utility rejection above, this application would then be granted the priority date of 8/24/00 which is to PCT/US00/23328 due to the priority map sent to the PTO which states that this application claims benefit to 60/096012, PCT/US99/12252, 09/380137, PCT/US00/23328. Application 09/380137 was unavailable for inspection and 60/096012 and PCT/US99/12252 do not disclose the polynucleotide is over expressed in tumor, thus there is no asserted utility for detection in tumor. The priority stands because there is no substantial utility for the polypeptide of SEQ ID NO:2

14. The rejection of claims 42-45, 47, 50-51 under 35 U.S.C. 102(b) as being anticipated by Feng et al (WO 99/24836, published 5/99) is maintained. This rejection

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is being made due to the priority granted and is consistent with the enablement because for a 102 rejection the art must teach how to make.

The response filed 2/2/04 has been carefully considered but is deemed not to be persuasive. The response states that the Fang disclosure discloses no utility and is therefore not enabled and cites case law that states that in a Mullan reference for a transgenic mouse it was found to be undue experimentation to produce such and as an anticipatory reference it was not enabled (see page 12-13 of response). In response to this the Fang reference discloses the SEQ ID NO:2 and fusion proteins and it is enabled because it teaches the sequence of SEQ ID NO:2. The reference does not need to disclose a utility, for anticipation all that is needed is how to make and that is taught by the sequence itself as stated in the rejection. The Mullan circumstance is not even on subject because the claims in the instant application are only to a SEQ ID NO and no function. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

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Thus viewed as a whole, the Polla disclosure shows that the natural result flowing from the operation as taught would result in alignment of the laser light over the hair follicle, as claimed. This was true even though Polla did not mention the goal of hair removal. Therefore, the Court held that the 192 patent was invalid as anticipated.

"Inherency is not necessarily coterminous with the knowledge of those skilled in the art ... Artisans of ordinary skill in the art may not recognize the inherent characteristics of the prior art."

190 F.3d at 1347

15. The rejection of claims 42-51 under 35 U.S.C. 102(b) as being anticipated by Baker et al (WO 99/63088, published 12/99) is maintained. This rejection is being made due to the prior art and is consistent with the enablement because for a 102 rejection the art must teach how to make.

The response filed 2/2/04 has been carefully considered but is deemed not to be persuasive. The response states that the priority is 8/24/00 because of the utility and the declaration of Dr. Grimaldi in the 131 declaration states that the inventors antedate the Baker reference (see page 13-14 of response). In response to this argument, the priority date is granted to be the instant filing date because of a lack of utility.

Therefore, a 131 declaration can not antedate the Baker reference.

Conclusion

16. No claim is allowed.

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17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,

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1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER